

The McKernan patent discloses an obturator for use in surgical procedures. The obturator has an elongated member with an instrument-receiving groove. This groove has an open top. (Col. 2, lines 31-32 and reference number 48 in Figure 1). The groove of the McKernan patent is distinct from a hollow shaft or a lumen, and the obturator is not a needle.

Because independent claims 1, 8 and 17 of the present application each contain a limitation, a hollow shaft or lumen, not disclosed by the McKernan patent, they cannot be anticipated by the McKernan patent. Claims 2-6, 9-15, and 18 depend, directly or indirectly, from these independent claims, and, therefore, they cannot be anticipated by the McKernan patent for at least the same reason. Accordingly, withdrawal of this rejection under 35 U.S.C. § 102 is respectfully requested.

Furthermore, the present invention would not be obvious to one of ordinary skill in the art, based on the McKernan patent. Because the device of the McKernan patent is used to introduce surgical tools into the body, it will at times be necessary or desirable to remove the device after the surgical tools have been introduced. (Col. 3, lines 7-15). Removal of the McKernan device without removal of the surgical tool would not be possible, if the device were to have a shaft or lumen, instead of a groove. Thus, the device of the McKernan patent would not be functional for this intended purpose if modified to have a hollow shaft or a lumen instead of a groove. Therefore, there would be no motivation for one skilled in the art to modify the device of the McKernan patent to include a hollow shaft or lumen. In addition, the McKernan patent does not teach or suggest a cutting surface on a needle. Thus, the McKernan patent cannot render the present invention obvious.

B. Claims 16, 17, 18, 20, and 21 are rejected as being anticipated by Gross 4,781,691 ("the Gross Patent"). This rejection is respectfully traversed.

The Gross patent discloses a method comprising the steps of: pushing a needle into the epidural space; feeding a catheter through the needle and into the space; and, removing the needle while holding the catheter stationary.

Claim 16 of the present application comprises as a first limitation: "pushing a needle into the epidural space with a cutting surface of the needle substantially parallel to the dura fibers"

of the patient, wherein the needle comprises a substantially straight cutting surface.” The Gross patent does not disclose that the cutting surface of the needle is inserted substantially parallel to the dura fibers of the patient. Furthermore, the needle of the Gross patent lacks the cutting surface of the instant device, having only a typical piercing point common to such needles (Col. 3, lines 60-62 and reference number 20 in Figures 2 and 3). The ability to separate dura fibers without severing them is an advantage of the present invention. The requirement that the needle be inserted with a cutting surface substantially parallel to the dura fibers of the patient is a limitation of claim 16 that is not disclosed in the Gross patent. Because the Gross patent lacks an element necessary to the method of claim 16, it cannot anticipate this claim. Accordingly, withdrawal of the rejection of claim 16 is respectfully requested. Additionally, in view of the distinct functionality difference between the Gross patent and the present invention, the teachings of the Gross patent could in no way render claim 16 obvious to one skilled in the art.

Claim 17 is directed to a needle kit including a medical needle of the invention, which includes a cutting surface on the needle. Gross discloses needles with reduced diameters for spine anesthesia. Because Gross does not disclose a needle with a cutting surface for minimizing damages to dura fibers, it cannot anticipate claim 17. Claims 18 and 20-21 depend from claim 17, and, therefore, cannot be anticipated by the Gross patent for at least the same reason. Therefore, withdrawal of this rejection is respectfully requested.

In addition, Gross does not teach or suggest a cutting surface on the needle. It cannot render claim 17 obvious. Claims 18 and 20-21 depend from claim 17, and should be patentable for at least the same reason.

### **III. Rejection under 35 U.S.C. § 103(a)**

- A. Claim 7 is rejected under 35 U.S.C. § 103 as obvious over the McKernan patent and over The McKernan patent in view of Takai et al., 4,945,895 (“the Takai patent”). This rejection is respectfully traversed.

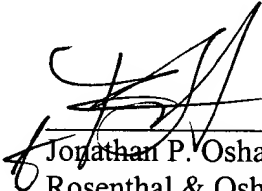
Claim 7 depends from claim 1. For reasons stated above, the McKernan patent cannot render claim 7 obvious. The Takai patent discloses methods and apparatuses for inserting

optical fibers into the body. It does not disclose a needle having a cutting surface for minimizing damages to dura fibers. Because the Takai patent does not teach or suggest what is missing in the McKernan patent, combination of these references cannot render claim 7 obvious. Accordingly, withdrawal of the rejection is respectfully requested.

Applicant believes this reply to be fully responsive to all outstanding issues and place this application in condition for allowance. If this belief is incorrect, or other issues arise, do not hesitate to contact the undersigned or his associates at the telephone number listed below. Please apply any charges not covered, or any credits, to Deposit Account 50-0591 (Reference Number 06570/002002).

Respectfully submitted,

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